Centrale
Commissie
Mensgebonden
Onderzoek

Explanatory note

Codes and document titles for CTIS submission

We request you to adhere to the structure of annex I CTR when naming your documents. Below you will find examples of the correct coding and document titles for your documents. You are requested to fill in the necessary data in the marked grey fields of the document filename. The documents must have unique document titles – please do not use identical titles. Do not include version number and date into filename.

Codes and document titles

B. Cover letter
B1. Cover letter [EU CT number]

D. Protol
D1. Protocol [EU CT number]
D1. Protocol synopsis_ENG [EU CT number]
D1. Protocol synopsis_NL [EU CT number]
D2. Protocol_modification no [number] [EU CT number]
D3. DSMB Charter [EU CT number]
D4. Patient facing documents [questionnaire, diary] *(if applicable*)

E. Investigator's Brochure
E1. IB [product name]

F. Documents GMP compliance (if applicable)
F1. GMP declaration
F2. QP declaration
F3. Other statements/licences *(e.g. import license*)

G. Investigational Medicinal Product Dossier
G1. IMPD_Q [product name]
G1. IMPD_E-S [product name]
G2. SmPC [product name]

H. Auxiliary Medicinal Product Dossier
H1. AxMPD [product name]

I.Scientific advice and paediatric investigational plan (PIP)
I1. Scientic advice [name organization]
I2. PedCo opinion
I3. PIP decision [name agency]

J. Labeling
J1. Label IMP_NL [product name]
J1. Label IMP_ENG [product name]
J2. Label AxMP_NL [product name]
J2. Label AxMP_ENG [product name]

K. Recruitment arrangement
K1. Template recruitment arrangements NL
K2. Recruitment material [description]

L. Subject information sheet, informed consent form, other subject information material
L1. SIS and ICF [description] (*e.g. SIS and ICF adults, SIS and ICF 12-16 yr)*
L2. Other subject information material [description] (*e.g. information leaflet adults)*

M. Suitability investigator
M1. CV Investigator [name investigator]
M2. DoI Investigator [name investigator]

N. Suitability facilities
N1. VGO [name investigational site]

O. Proof of Insurance or idemnification
O1. WMO trial participant insurance certificate
O2. Proof of coverage sponsor or investigator [name sponsor/trial site] (*if not included on VGO*)

P. Financial and other arrangements
P1. Template compensation trial participants, investigator, funding and other arrangements

R. Compliance GDPR
R1. Template on the collection and use personal data NL

S. Biological samples
S1. Template on the collection, use and storage of biological samples NL